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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,336	04/18/2000	Arne Holm	55503	1910
21874	7590	02/25/2004	EXAMINER	
EDWARDS & ANGELL, LLP			AUDET, MAURY A	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1654

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,336

Applicant(s)

HOLM ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-6, 8, 14 and 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7, 9-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-20 in the paper filed December 8, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL. Claims 1-25 are pending, claims 21-25 are withdrawn from consideration as well as claims 2, 4-6, 8, 14, and 20 (which do not read upon the elected invention, i.e. the method of making the elected compound), and claims 1, 3, 7, 9-13, and 15-19 are examined on the merits.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, and 9, and 11-13 recite the limitation "the *support*" and claim 10 recites the limitation "the *solid support*". There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claims be amended to the solid phase synthesis be described in line 12 of claim 1 so as to describe how the "solid support" or "support" is used in the invention.

Claims 1, 3, 7, 9-13, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At the outset, it is noted that the claims as drafted are unclear because the language is not drawn to the elected invention (a method of making the compound

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“H-Ala₁₀-Lys-OH”). Thus, the claims should be amended so as to only be drawn to the elected invention (a method of making the compound “H-Ala₁₀-Lys-OH”).

In claim 1, it is unclear what is meant by “the C-terminal amino acid in the *form* of an N-alpha-protected reactive derivative”? Additionally, it is unclear whether the 1st Ala or Lys is the C-terminal amino acid? Namely, it is unclear if the C-terminal amino acid has an “N-alpha-protected reactive derivative” or is just similar to such chemical modification? In either case, the claim must be amended to clarify the structure of the C-terminal amino acid.

In claim 1, it is unclear what is meant by “said C-terminal amino acid comprises a *presequence* comprising from 3 to 9 amino acid residues . . .”? Namely, the elected invention is a method of making the compound “H-Ala₁₀-Lys-OH”. Additionally, it is unclear whether the 1st Ala or Lys is the C-terminal amino acid? In either case, the elected compound does not contain a “presequence” (i.e. from 3 to 9 amino acid residues?) attached to either Lys or Ala (whichever, Applicant regards as the C-terminal). Furthermore, it appears that the presequence in step (d) may be “optionally” cleaved from the formed peptide (elected “H-Ala₁₀-Lys-OH”); which leaves open the option of the presequence being left on the elected peptide (“H-Ala₁₀-Lys-OH”), which would then constitute an invention not drawn to the elected subject matter (a method of making the compound “H-Ala₁₀-Lys-OH”). It is suggested that the term “presequence . . .” be deleted from step (b) of claim 1, as well as the language of step (d).

In claim 1, it is unclear what is meant by “coupling . . . optionally by means of a *linker*”? The claims must be amended to clarify whether the invention is coupled by a linker or not.

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Allowable Subject Matter

It is noted that claims 1, 3, 7, 9-13, and 15-19 have only been examined as drawn to the elected invention (a method of making the compound "H-Ala₁₀-Lys-OH"). The present method of making the compound "H-Ala₁₀-Lys-OH" was found to be free of the prior art, based on the steps of the method as claimed (notwithstanding the rejections above as to certain steps not being drawn to the elected invention). As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

February 21, 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER